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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,470	09/01/2006	Martin Scholz	0060.0002	1446

39878 7590 01/09/2008

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,470	SCHOLZ, MARTIN	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15 and 18-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

I. Claims 1-15 and 18-25 are pending.

Election/Restrictions

II. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

1. Claims 4, drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component for generating leukocyte stimulation and/or induction of tolerance is a specific **antigen other than viruses, bacteria, fungi, tumors, or allergen.**

2. Claims 4-6, and 18, drawn leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component for generating leukocyte stimulation and/or induction of tolerance is specific **antigen** from a specific **virus**.

3. Claims 4-5, drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component for generating leukocyte stimulation and/or induction of tolerance is a specific **antigen** from a specific **bacteria**.

4. Claims 4-5, drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component for generating leukocyte stimulation and/or induction of tolerance is a specific **antigen** from a specific **fungi**.

5. Claims 4-5, drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component for generating leukocyte stimulation and/or induction of tolerance is a specific **antigen** from a **tumor**.

6. Claims 4-5, drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component for generating leukocyte stimulation and/or induction of tolerance is a specific **antigen** from a specific **allergen**.

7. Claims 4-5, drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component for generating leukocyte stimulation and/or induction of tolerance is a specific **MHC molecule**.

8. Claims 4-5, drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance

wherein the component for generating leukocyte stimulation and/or induction of tolerance is a specific **co-stimulatory factor**.

9. Claims 4, drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix for embedding at least one component for generation generating a leukocyte stimulation and/or the induction of an immunological tolerance, c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component is **cell components or cell coatings.**

10. Claims 4-5, drawn to **leukocyte stimulation matrix** for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix for embedding at least one component for generation generating a leukocyte stimulation and/or the induction of an immunological tolerance, c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component is specific **antigen** from a specific **combination of antigens**.

11. Claims 14-15 and 24 drawn to **a process and method for stimulation of leukocytes and/or the induction of an immunological tolerance** comprising providing a leukocyte stimulation matrix having a) at least one carrier, b) a soluble matrix for embedding at least one component for generation generating a leukocyte stimulation and/or the induction of an immunological tolerance, c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance.

12. Claim 25, drawn to a **method for detecting** distribution of activated T-cell subtypes comprising providing a leukocyte stimulation matrix having a) at least one carrier, b) a soluble matrix for embedding at least one component for generation generating a leukocyte stimulation and/or the induction of an immunological tolerance, c) at least one

component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance.

Linking claims 1-3, 7-13, and 19-23 will be examined along with Groups 1-10 if any one of said Groups is elected.

Claims 1-3, 7-13, and 19-23 link inventions 1-10. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 1-3, 7-13, and 19-23. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions listed as Groups 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The US application 2003/0129214 A1 (published July 10, 2003 1996; PTO 892) teaches leukocyte stimulation matrix for induction of immunological tolerance comprising at least one carrier such as polyurethanes or biological material such as tendon or dermal collagen (see page 8, paragraphs 0070-0071, in particular), a soluble matrix from any suitable material such as hydrogel coated onto said carrier for embedding at least one component such as MCP-1 antagonist for induction of immunological tolerance such as inhibition of chronic inflammation at the site of implantation (see page 8, paragraphs 0074, page 3, 0034, claims 25-38 of application, in particular).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

III. Accordingly, Groups 1-12 are not so linked as to form a single general inventive concept and restriction is proper.

IV. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

V. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VI. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

VII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/
Patent Examiner
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January 4, 2008